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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,271	06/20/2003	Gregory R. Ley	279.603US1	6442

21186 7590 07/12/2005

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/601,271	Applicant(s) LEY ET AL.	
	Examiner Mark W Bockelman	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 4-27-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-6-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 11, 13-18, 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Erb et al USPN 6,436,119.

Erb et al shows a 60 and a rod tunneling too 24 inserted therein wherein the tube has a slit portion making it possible for the tube to be peeled back away from the rod member. Rod member is equipped with threads 95 and the proximal end that may hold a hypothetical lead that has a thread attached thereto to its end for pulling the lead through the tube. Function recitations directed to the specifics of a lead are given no patentable weight.

Claims 1-5, 11-15, 17-19, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldvogel USPN 5,061,245. Waldvogel shows a tunneling member that extends through a tube 11, the tunneling member having a rod portion 16 with a handle-

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holding member 17, 18 which includes removable sutures. The sutures are disclosed as holding graft members for pulling the graft through the tube, however the examiner considers them to be capable of attaching to a lead to pull through the tube as well.

Claims 1, 8-10, 11, 20-22 rejected under 35 U.S.C. 102(b) as being anticipated by Clarke USPN 3,871,379. Figure 5-24 show a first and second rod, 18-19 attached to form a pair of forceps. The biased jaws of the forceps are capable of tunneling through tissue and have serve as a gripping means. A hypothetical lead having a suture at a distal end could be pulled back through the catheter 14.

Claims 1, 3-5, 8-10, 11-15, 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al USPN 5,690,648. Fogarty shows a forceps device having a rod portion 26 for grasping a tail of an electrode for pulling it through outer tube 20 (column 6 lines 31-41). While teaching an insertion method it is apparent that the electrode mady be removed by grasping the electrode with the forceps already inserted in the tube and pulling back so as to pull the electrode through the tube. Flexible and rigid are relative terms and the trocar tube 20 can be considered either depending upon what it is compared too.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al USPN 6,436,119, Waldvogel USPN 5,061,245, Clarke USPN 3,871,379. To have coated the inner tube in each of the references with a lubricious coating to decrease friction would have been notoriously old and well known

Applicant's arguments filed 4-27-2005 have been fully considered but they are not persuasive. While applicant cites no legal precedent to 1) Consider a explanation by the examiner of how a device is capable of performing a function as a taking of official notice 2) Require the examiner to produce a reference the examiner nevertheless has cited such a reference in listing Malonek et al on the enclosed 892. The examiner believes applicant to be wrong on these points of law and does not feel the need to include it in the rejections until applicant provides the legal basis for their assumptions.

The examiner has demonstrated how the devices are capable of performing the recited function with a suture holding the distal end of a lead for pulling it through a tube. Applicant could easily overcome many, but not all, of the rejections by reciting the combination of the tube, tunneling rod, and electrode lead.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

July 7, 2005


MARK BOCKELMAN
PRIMARY EXAMINER